

### **REMARKS**

Claims 51 and 60-75 are presently pending. None of the claims have been amended or cancelled. Therefore, claims 51 and 60-75 remain pending in the present application.

#### **Claim Rejections Under 35 U.S.C. § 103**

Claims 51 and 60-75 were rejected under 35 U.S.C. § 103(a) as being obvious over the English translation of Japanese Patent No. 3-146679 to Haruyuki et al. ("Haruyuki") in view of U.S. Patent No. 5,571,017 to Niznick ("Niznick").

For at least the reasons stated below, the Applicants respectfully submit that the Examiner has not set forth a *prima facie* case of obviousness under 35 U.S.C. § 103 and request that these rejections be withdrawn.

#### **I. The Haruyuki Reference**

The Examiner contends that "since a similar type of etching process is used . . .", Haruyuki's surface would "inherently" be the same as the Applicants' surface. Office Action, page 4. If the Examiner is correct in citing Haruyuki for producing a similar surface from a similar process, then it should be evident that the surfaces are, in fact, similar. Based on the Applicants' significant testing set forth in a Declaration under 37 C.F.R. § 1.132 by Dr. Prabhu Gubbi, submitted on June 26, 2003, the Applicants respectfully submit that (i) Haruyuki's roughened surface does not "inherently" correspond to the Applicants' surface and (ii) Haruyuki's surface cannot be duplicated.

Regarding Haruyuki, the English translation teaches a method of treating the surface of a titanium implant with a solution of hydrofluoric acid, which is then followed by post-treatment with a solution of hydrofluoric acid and hydrogen peroxide. The initial treatment with a solution of hydrofluoric acid is said to create pits which have sharp edges and sharp spines. Then, the post-treatment with the solution of hydrofluoric acid and hydrogen peroxide is performed to **smoothen** the sharp edges and sharp spines, which may cause tissue irritation. Haruyuki, p. 4, col. 1. Thus, Haruyuki does not teach a second treatment that **roughens** the surface from which the native oxide had been removed. Haruyuki teaches a post-treatment used to smoothen the sharp edges and sharp spines produced by the first treatment, rather than to further roughen the surface.

Thus, the Applicants respectfully disagree with the Office Action's statements that "Haruyuki does not teach smoothening the surface" and "Smoothness is not explicitly discussed." Office Action, p. 4. Smoothness is, in fact, explicitly discussed at page 4, column 2 of the English translation of Haruyuki, which states, "Dipping in a mixed aqueous solution of HF and H<sub>2</sub>O<sub>2</sub> in the posttreatment functions to smooth the sharp edges and sharp spines that appear at the microscopic depressions produced during the pretreatment" (emphasis added).

Additionally, from Haruyuki's photographs, it is clear that the surfaces have a topography different from the Applicants' surface, perhaps due to the fact that the Applicants further roughen the surface after the native oxide is removed, while Haruyuki smoothens the surface created by the first step. To further compare Haruyuki's results with the Applicants' results, the Applicants have conducted several experiments. The results were reported in the Declaration under 37 C.F.R. § 1.132 by Dr. Prabhu Gubbi. The Applicants' surface (*i.e.*, the Osseotite® surface) is shown in Exhibit A of the Gubbi Declaration. The results of repeating Haruyuki's experiments are reported in Exhibit B of the Gubbi Declaration.<sup>1</sup> It is clear from the photomicrographs presented in Exhibit A of the Gubbi Declaration that the Applicants' Osseotite® surface is not obtained when the methods of Haruyuki's examples, shown in Exhibit B, are repeated. Furthermore, Haruyuki's photographs in Exhibit B do not resemble the surface achieved when Haruyuki's tests were repeated by Dr. Gubbi, which leaves the Applicants questioning Haruyuki's methodology.

While the Examiner is encouraged to review the results of Dr. Gubbi's extensive Declaration in detail, for the Examiner's convenience, a one-page comparison including selected photographs from Dr. Gubbi's Declaration is included in Exhibit 1. The purpose of this one-page comparison in Exhibit 1 is to easily compare (i) the surface that Haruyuki illustrated in Haruyuki's Japanese patent application as the desired surface (Gubbi Decl., Ex. B, Example 2), (ii) the surface that resulted from Dr. Gubbi's attempt to replicate Haruyuki's process, and (iii) the commercial Osseotite® surface according to the claimed invention.

In Exhibit 1, the first row shows the surface after Haruyuki's first step (Haruyuki's FIG. 2) in which a titanium surface is treated with 4 % HF for 1 minute, creating a rough surface. Haruyuki's FIG. 4 shows a surface after two steps, including Haruyuki's "post-treatment" with 4

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<sup>1</sup> Exhibits C and D to Dr. Gubbi's Declaration relate to tests showing results of acid-etching with various mineral acids, and tests showing results of grit-blasting plus various acid-etching steps, respectively.

% HF and 8 % H<sub>2</sub>O<sub>2</sub> for 15 seconds. Haruyuki's FIGs. 2 and 4 appear very similar, as might be expected, since Haruyuki teaches that the second treatment was only to "smoothen" the sharp edges and sharp spines created in his first treatment.

In the second row of Exhibit 1, the attempt to duplicate Haruyuki's process are shown. These results are taken from Exhibit B of Dr. Gubbi's Declaration. Clearly, the process set forth in Haruyuki could not be repeated to produce the results that Haruyuki allegedly obtained.

In the third row of Exhibit 1, a surface according to the Applicants' invention is disclosed after the first step (treatment with HF) and after the second step (mixture of HCl and H<sub>2</sub>SO<sub>4</sub>). The first step produces a relatively smooth surface. The second step produces a roughened surface.

Accordingly, in addition to the fact that Haruyuki discloses a process that could not be repeated by a skilled artisan (Dr. Gubbi), the surfaces disclosed by Haruyuki are different from the claim surfaces. Thus, the Applicants respectfully suggest that the extensive testing that they have done completely disproves the Examiner's position that if "a similar type of etching process is used [by Haruyuki] to form irregularities on the surface of the same material as claimed", then "the surface irregularities of Haruyuki . . . would inherently be the same as those set forth claims." Office Action, p. 4.

## II. Claims 51 and 60-62

Independent claim 51 recites:

- a smooth head portion for receiving a dental restoration component;
- a roughened region located on said threaded portion and extending to said lowermost end of said implant; and
- the roughened surface is uniformly acid etched and characterized by having a substantially uniform array of irregularities having peak-to-valley heights not greater than about 10 microns.

In other words, claim 51 requires, below the smooth head portion, a uniformly acid-etched surface extending from the threaded portion all the way to the lowermost end, and that this uniformly acid-etched surface has a substantially uniform array of irregularities having peak-to-valley heights not greater than about 10 microns.

Haruyuki was cited by the Examiner for allegedly having the acid-etched surfaces defined by claim 51. As mentioned above, the Applicants dispute the Examiner's position.

Niznick was cited for teaching different regions of roughness and the location for the different regions of roughness. Yet, as discussed below, Niznick's teaching of where, and to what degree, to roughen the implant is substantially different from the invention of claims 51, 60, and 62, and it is substantially different from Haruyuki's teaching.

**A. Niznick and Haruyuki Teach Away From Their Combination**

MPEP § 2123(II) and the Office Action's remarks regarding this section suggest that a reference's disclosure is not limited to preferred embodiments and that alternative embodiments – even if less preferred – are considered to be taught by the reference. Office Action, p. 5. The Applicants do not disagree with this statement but, rather, submit that this section is not applicable here. As noted in detail below, Haruyuki does not teach etching an implant surface to a depth exceeding 5 microns as an alternative embodiment. Rather, Haruyuki teaches that doing so could lead to a potentially grave situation for the patient, including causing cancer. Likewise, Niznick does not teach average peak-to-valley distances of an implant surface texture below 25 microns as an alternative embodiment. Rather, Niznick teaches that the implant surface **must** be exceedingly **rough**, i.e., 25 microns or greater.

The Applicants also submit that the Office Action has failed to adequately address the Applicants' position that Niznick and Haruyuki teach away from their combination. In attempting to respond to this position, the Office Action relies on MPEP § 2123(II), which is titled "Nonpreferred and Alternative Embodiments Constitute Prior Art." This section, however, applies to Applicants' position that a reference teaches away from the **invention itself** (as the Applicants argue in a separate position detailed below), not that a reference teaches away from **its combination** with another reference. MPEP § 2123 states, "A known or obvious composition does not become patentable simply because it has been described as somewhat inferior to some other product for the same use." MPEP § 2123 (II) (citing *In re Gurley*, 27 F.3d 551, 554 (Fed. Cir. 1994)). Thus, § 2123 focuses on the relationship between the applied reference and the claimed invention, **not** on the relationship between the applied reference and another applied reference on which an obviousness rejection is based.

The section of the MPEP relied upon here by the Applicants is MPEP § 2145(X)(D)(2), titled "References Cannot Be Combined Where Reference Teaches Away from Their Combination." In this case, both Niznick and Haruyuki teach away from their combination for the reasons set forth below.

Haruyuki is very specific about what type of surface he desires. After providing several different examples using modified process steps, Haruyuki concludes that the microscopic depressions should have an average depth of 0.5 to 5 microns. Haruyuki, p. 4, col. 1, ll. 1 to 5. Haruyuki also explains his reasoning:

The bases for specifying an average depth in the range from 0.5 to 5  $\mu\text{m}$  are as follows: the anchoring effect between the bone and biorepair member is low at an average depth below 0.5  $\mu\text{m}$ ; an average depth in excess of 5  $\mu\text{m}$ , although providing a high anchoring effect, tends to result in the appearance of sharp spines and sharp edges at the ridge lies between depressions, which can cause tissue irritation (possibly a trigger for cancer).

Haruyuki, p. 4, col. 1, lines 22 to 32 (emphasis added). In other words, Haruyuki's primary concern is that if the depth of the microscopic depressions on the implant's surface exceeds 5 microns, then there is a detrimental effect, which can possibly lead to a grave situation for the patient – **cancer**. Haruyuki tested various types of processes and discards several of them because they produced the "sharp edges" and "sharp spines," which lead to the peak-to-valley height being greater than 5 microns and the associated detrimental effects. *See, e.g.*, Haruyuki, pp. 7-8.

So, what does Niznick teach? Compared to Haruyuki, Niznick teaches that the implant's surface should be **exceedingly** rough. In fact, Niznick teaches that the main portion of the implant's surface should be **at least five times greater** than the surface specified by Haruyuki.

When describing the first embodiment of FIG. 1, Niznick states:

The darkened, external, threaded, middle region 14 is relatively rough, with the average peak-to-valley distance of the surface texture **being 25 microns or greater** which is at least 25% greater than the roughness of the uncoated self-tapping threads 8 at distal end or uncoated proximal end surfaces 2 and 3.

Niznick, col. 7, ll. 11-14 (emphasis added) And, when describing the only other illustrated embodiment, which is shown in FIG. 2, Niznick repeats the same teaching:

Implant 20 has a darkened, external, threaded, middle region 27 with a surface that is relatively rough, with the average peak-to-valley distance of the surface texture **being 25 microns or greater** which is at least 25% greater than the roughness of the uncoated self-tapping threads 21 at [the] distal end and relatively smooth uncoated proximal end 26.

*Id.*, col. 7, ll. 42-47 (emphasis added).

Consequently, while Haruyuki teaches the skilled artisan to avoid surfaces where the peak-to-valley height of the surface texture is greater than 5 microns because of potential biological problems, such as cancer, Niznick teaches that same skilled artisan to employ a surface where the peak-to-valley height of the surface texture is 25 microns or greater. In fact, the exceedingly rough implant is Niznick's invention, as can be seen by reviewing Niznick's claim 1.

The Office Action states that "the different dimensions [of Haruyuki and Niznick] alone do not make them incompatible." Office Action, p. 5. But, the differences between the surface texture taught by Haruyuki and the surface texture taught by Niznick do not just relate to the dimensions of the surface texture – they also relate to the surface texture itself. Niznick teaches that the surface texture with the peak-to-valley heights of 25 microns or greater should be created from an HA (hydroxyapatite) coating, TPS (titanium plasma spray) coating, or grit blasting, all of which introduce foreign matter to the underlying implant surface. *Id.*, col. 7, ll. 17-18, 47-48.

Haruyuki knew about these types of material-adding processes that can increase the surface roughness. But, Haruyuki, who touts his HF acid-etching process, teaches the skilled artisan of the problems associated with these types of material-adding process, such as introducing "biotissue contamination" to the patient and/or operational complexity and high-cost. Haruyuki, p. 3, col. 1. As such, this is yet another direct contradiction between the Haruyuki and Niznick teachings on surface texture.

It is axiomatic that the entire teachings of the references must be considered when determining obviousness. When doing so here, the skilled artisan would never combine the teachings of Niznick with those of Haruyuki to produce Applicants' invention of claim 51. Prior art references simply cannot be combined where the references teach away from their combination. *In re Grasselli*, 713 F.2d at 743, (Fed. Cir. 1983); MPEP §§ 2143, 2145.

**B. Niznick Teaches Away From The Invention of Claim 51**

Claim 51 requires a smooth head portion and a threaded portion with a roughened region extending to the lowermost end, wherein the roughened region has a substantially uniform array of irregularities having peak-to-valley heights no greater than about 10 microns. This configuration is not disclosed in Niznick, and Niznick actually teaches away from it with his three-part surface roughness.

Niznick teaches that the implant's lowermost end at the self-tapping region 8 (FIG. 1) or 21 (FIG. 2) should be roughened up to a peak-to-valley height of 20 microns. Niznick, col. 5, ll. 16-20, col. 7, ll. 11-15, 41-45. Niznick considers this surface "relatively smooth" compared to the middle threaded region 14 (col. 7, l. 26), which has the peak-to-valley height of **at least 25 microns** brought about through a material-adding process, such as HA coating, TPS coating, or grit blasting. In fact, these extremely rough surfaces at the **three** distinct locations (*i.e.*, (i) the distal end where the self-tapping feature resides, (ii) the proximal end at the top of the implant, and (iii) the middle region with the peak-to-valley heights of **at least 25 microns**) are the subject matter of Niznick's claim 1. As such, what Niznick considered to be a "relatively smooth" surface is much rougher than the Applicants' acid-etched surface.

Claim 51 requires a "smooth head portion" and a threaded portion with a roughened region **being uniformly acid-etched and extending to the lowermost end.** The roughened region has a substantially uniform array of irregularities having peak-to-valley heights **no greater than about 10 microns.** To make this rejection, the Office Action has ignored the fundamental teaching of Niznick – the extremely rough surface of **at least 25 microns** (which is not, of course, uniformly acid-etched) – that teaches away from claim 51. A prior art reference that teaches away from the claimed invention is a significant factor to be considered in determining obviousness.

Because the proposed combination of Haruyuki and Niznick is improper for several reasons, the Applicants respectfully request the withdrawal of the rejections of claims 51, and 60-62, which are believed to be in a condition for allowance.

### III. Claims 63-67

Independent claim 63 recites:

- **a head portion having a smooth machined surface** and for receiving a dental restoration component;
- a threaded portion including a self-tapping region adjacent to said lowermost end;
- said threaded portion having an acid-etched surface;
- said acid-etched surface **extending to said lowermost end of said implant and within said self-tapping region;** and
- said acid etched surface having a substantially uniform array of irregularities having peak-to-valley heights not greater than about 10 microns.

As noted above with respect to claims 51 and 60-62, the combination of Haruyuki and Niznick fails because (i) Haruyuki and Niznick are directly contradictory to each other in several respects relative to the type of surface texture they teach, and (ii) Niznick teaches away from several aspects of the claimed acid-etched surface. Accordingly, for the reasons set forth above, claims 63-67 are not obvious over the applied references.

Additionally, independent claim 63 includes limitations regarding the self-tapping feature of the dental implant and, specifically, that the acid-etched surface with the substantially uniform array of irregularities is located within the self-tapping feature. Niznick, on the other hand, does **not** teach an acid-etched surface that extends along the threaded portion of the dental implant, into the self-tapping region, and to the lowermost end of the implant. Again, the middle threaded portion of Niznick's implant that is roughened does **not** extend to the lowermost end of the implant or into the self-tapping region. As such, Niznick not only does not suggest such a configuration of claims 63-67, but actually teaches away from it. Simply put, Niznick fails to overcome the deficiencies of Haruyuki.

The Applicants respectfully request the withdrawal of the rejections of claims 63-67. Claims 63-67 are believed to be in a condition for allowance.

#### IV. Claims 68-75

Independent claim 68 recites:

- **a head portion having a smooth machined surface** and for receiving a dental restoration component;
- a threaded portion including a self-tapping region adjacent to said lowermost end;
- said threaded portion including a cylindrical section and a tapered section immediately adjacent to said lowermost end, said cylindrical section being longer than said tapered section;
- said threaded portion having an acid-etched surface;
- said acid etched surface **extending from said lowermost end of said implant and into said cylindrical section of the threaded portion**; and
- said acid etched surface having a substantially uniform array of irregularities having peak-to-valley heights not greater than about 10 microns.

As noted above with respect to claims 51 and 60-62, the combination of Haruyuki and Niznick fails because (i) Haruyuki and Niznick are directly contradictory to each other in several



respects relative to the type of surface texture they teach, and (ii) Niznick teaches away from several aspects of the claimed acid-etched surface. Accordingly, for the reasons set forth above, claims 68-75 are not obvious over the applied references.

Claim 68 requires cylindrical and tapered sections and a self-tapping region within the tapered section. An acid-etched surface **extends from the lowermost end, through the self-tapping region, and into the cylindrical section**. The acid-etched surface has a substantially uniform array of irregularities having peak-to-valley heights no greater than about 10 microns. Niznick, on the other hand, does **not** teach an acid-etched surface extending from the lowermost end, through the self-tapping region, and into the cylindrical section. The middle threaded portion of Niznick's implant includes an extremely rough surface having peak-to-valley heights of greater than 25 microns. Of course, Niznick's roughened surface does **not** extend from the lowermost end of the implant, into the self-tapping region, and into the cylindrical section. As such, Niznick not only does not suggest the configuration of claims 68-75, but actually teaches away from it.

The Applicants respectfully request the withdrawal of the rejections of claims 68-75. Claims 68-75 are believed to be in a condition for allowance.

#### **V. Dependent Claims 61, 67, and 72**

The Applicants contend that claims 61, 67, and 72 are separately patentable for the reason that not all of the elements of claims 61, 67, and 72 are taught in Haruyuki or Niznick. Specifically, each of these dependent claims recite that the second acid solution (which produces the acid-etched surface) is a mixture of sulfuric and hydrochloric acids. Haruyuki only discloses an HF and H<sub>2</sub>O<sub>2</sub> solution. Haruyuki's two-step process differs from that of the Applicants' process and, more importantly, differs in the appearance of the resulting surfaces. Therefore, the claims that recite the acids used in the Applicants' two-step treatment should be patentable over Haruyuki. And, Niznick provides no suggestion whatsoever that would lead one skilled in the art to utilize the inventions set forth in dependent claims 61, 67, and 72.

#### **VI. Dr. Porter's Declaration Establishing Secondary Evidence of Non-Obviousness**

To overcome the obviousness rejections that were set forth by the Examiner, the Applicants previously submitted a Rule 132 Declaration from Dr. Porter (the "Porter Declaration") that sets forth evidence of nonobviousness. That Declaration was submitted by the Applicants on April 29, 2002.

The Declaration establishes the nexus between the commercial Osseotite® surface and the claimed invention. The commercial Osseotite® surface is set forth in Exhibit A of the Porter Declaration. Furthermore, several catalogs were included as Exhibit B, which show a myriad of examples of the overall screw-type structure of the dental implants that embody the Osseotite® surface. Without question, the dental implants with the Osseotite® surface that are discussed by Dr. Porter are covered by the pending claims that there the subject of this appeal.

Dr. Porter established a rapid increase in sales of implants having the Osseotite® surface relative to other implants. He further establishes evidence of **clinically-proven** enhanced osseointegration due to the Osseotite® surface. Most importantly, Dr. Porter establishes that numerous competitive companies, in attempting to sell their dental implants, compare their surfaces with the Osseotite® surface. These “me-too” competitive products and their associated statements are competitive flattery indicating that the Osseotite® surface is the “gold standard” of implant surfaces.

In response to the Porter Declaration, the Office Action states that “the claimed product-by-process steps are quite broad such that they are not commensurate in scope with the process steps used to make Applicant’s samples”. Office Action, p. 5. That simply is not true. Dr. Porter’s Declaration discusses the Osseotite® surface in detail in paragraphs 3 and 5. That language tracks the language of the claims. And, Dr. Porter discloses the structure of these implants in the catalogs that are included in Exhibit B.

In summary, the Porter Declaration is yet another reason that the pending claims are not obvious.

### **Copending Applications**

In response to the Office Action’s request on page 6, the following is a list of copending applications claiming priority back to U.S. Patent Application Serial No. 08/351,214 (now abandoned), to which the present application also claims priority. The claims of each of these applications are believed to be stored in image format (i.e., the IFW system) and/or published.

| <b>Serial No.</b> | <b>Publication No.</b> |
|-------------------|------------------------|
| 11/651,115        | 2007/0108162           |
| 12/069,867        | 2008/0135521           |
| 12/070,487        | Not yet published      |

**Conclusion**

It is the Applicants' belief that all of the claims are now in condition for allowance and action towards that effect is respectfully requested. The Applicants respectfully request that a timely Notice of Allowance be issued in this case. If there are any matters which may be resolved or clarified through a telephone interview, the Examiner is requested to contact the undersigned attorney at the number indicated. The Commissioner is authorized to charge any fees that may be required (except for payment of the issue fee) to Nixon Peabody LLP, Deposit Account No. 50-4181, Order No. 247168-000035USC1.

Dated: July 7, 2008

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